SUPPORT FOR THE AMENDMENTS

The amendments to Claims 9, 15 and 21 and newly-added Claims 33-41 are supported by the specification, particularly the Examples. Accordingly, no new matter is believed to have been added to the present application by the amendments submitted above.

REMARKS

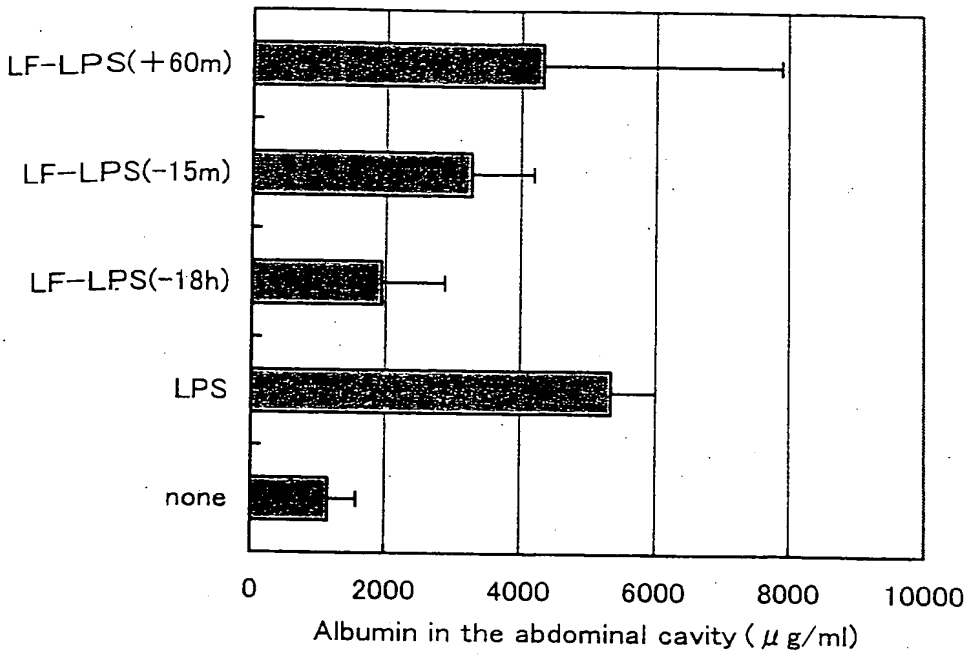
Claims 9-26 and 33-41 are now pending, upon entry of the amendments submitted above. Favorable reconsideration is respectfully requested.

Applicants would like to thank Examiner Mohamed for the helpful and courteous discussion held with their representative on November 29, 2006. During the discussion, the claim amendments submitted above were discussed. Applicant's representative explained that Nitsche fails to disclose or suggest administering human-type lactoferrin to a person prior to infection by bacteria which produce lipopolysaccharide in to alleviate symptoms from lipopolysaccharide-induced inflammation resulting from infection by bacteria. The following remarks expand on the discussion with the Examiner.

The present invention relates to a method for alleviating a symptom from lipopolysaccharide-induced inflammation resulting from infection by bacteria which produce lipopolysaccharide, comprising administering to a person orally or parenterally, ***prior to the infection by the bacteria***, an effective amount of human-type lactoferrin for a time and under conditions effective to alleviate said symptom, wherein said symptom is accumulation of body fluid containing albumin at the inflammatory site.

See Claim 9. See also Claims 15 and 21.

As shown in the Examples of the present application, the Inventors administered human-type lactoferrin before the administration of lipopolysaccharide (LPS) to effectively alleviate symptoms of lipopolysaccharide-induced inflammation. In particular, in Example 4 human-type lactoferrin was administered (1) 18 hours before, (2) 15 minutes before and (3) 60 minutes after the administration of LPS. A much better result was observed in (1) and (2) as compared to (3). Those data are shown in Figure 6 of the present application, which is reproduced below:



Effect of human-type lactoferrin on albumin accumulation in the abdominal cavity under LPS induction: Difference in the time of lactoferrin administration
(- before administration time + after administration time)

The rejections of the claims under 35 U.S.C. §102(b)/§103(a) over Nitsche is respectfully traversed. Nitsche fails to disclose or suggest the claimed methods.

Nitsche describes administering lactoferrin to inhibit endotoxins (see the Abstract). The reference fails to describe or suggest administering human-type lactoferrin to a person prior to infection by bacteria which produce lipopolysaccharide. In fact, in the *in vivo* tests described in Examples 3 and 4 of Nitsche, bacteria were inoculated *before* administration of lactoferrin. Nitsche certainly fail to suggest the striking experimental results set forth in the specification of the present application discussed above.

In view of the foregoing, the claimed methods are neither anticipated by nor obvious over Nitsche. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

The rejections of the claims under 35 U.S.C. §112, first and second paragraphs, are believed to be obviated by the amendments submitted above. The newly-added claims are supported by the specification and believed to be definite within the meaning of 35 U.S.C. §112, second paragraph. Accordingly, withdrawal of this ground of rejection is respectfully requested.

An Information Disclosure Statement (IDS) is submitted herewith. The IDS lists an abstract for a poster presentation entitled "Lactoferrin Ameliorates Severe Albumin Extravasations and Neutrophilia in LPS Injected Neonatal Rats." A publication date is not explicitly listed. The conference was held on May 4-9, 2001. However, in the papers accompanying the abstract, the Abstract Submission form indicates that the abstracts must be submitted by March 9, 2001. The authors of the abstract and the inventors of the present application are the same except that (1) the abstract lists Y. Aoyama but that individual is not named as an inventor of the present application and (2) the present application names Yumi Tsukamoto as an inventor but that individual is not listed on the abstract. Consideration of the IDS is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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